SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING NOVEMBER 23, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on November 23, 1999, at 11 a.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (USEPA) Region 3. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The list of parking lot issues includes 5 items from NELAC V (Attachment C). Attachment D is a listing of frequently asked questions. Attachment E presents the QS Committee approach to handling comments, comment acknowledgment form letter, guiding principles for reviewing comments and the standard, and commenter template. *The purpose of the meeting was to discuss action items, current status of Chapter 5, homework, electronic data (GALP) and concerns from presentations, and the agenda for the Fifth NELAC Interim Meeting (NELAC Vi).*

ACTION ITEMS FROM PREVIOUS MEETINGS

Department of Defense

Mr. Cliff Glowacki and members of the QS Air Sub-Committee met with Department of Defense (DOD) representatives to discuss comments. The result of the meeting was to distinguish field QC from anything that is conducted in the laboratory. As a result, all field-related QC is eliminated from Appendix 5. All parties were comfortable with this division.

Glossary

Previously, Mr. Slayton contacted both the NELAC Program Policy and Structure Committee and the NELAC Board of Directors and recommended that (1) all items in the NELAC Glossary (Chapter 1) be cross-referenced to the specific committee concerned, and (2) when changes are proposed to entries in the Glossary, the committees which are affected by these changes will be notified and allowed to review the proposed change. The Program Policy and Structure Committee was not in favor of this recommendation, but will continue to notify all committees when any changes are proposed to the glossary. This resolution was agreeable to the QS committee.

Updated Material on Radiochemical Testing

Mr. Slayton confirmed that the most recent version of D.4 (Radiochemical Testing) from Mr. Donivan Porterfield is included in the appendix that will be available at NELAC Vi. Because he will not be able to attend the meeting, arrangements are being made so that Mr. Porterfield, an expert on radiochemical testing, can provide input/information during the December 14, 1999 3:30-4:30 p.m. session. The clarification will be made during the session that Mr. Porterfield is a former member of the QS committee and has been invited to provide expertise, but that he is not a current member of the QS committee.

NELAC Vi QS Committee Agenda

The committee discussed the flexibility in the agenda for the QS Committee meeting at NELAC Vi. The discussion was focused on how to deal with extra time should the sessions on air testing and radiochemical testing finish early. The committee anticipates that these may finish early if experts in these subject areas are not present. They agreed that it would not be advisable to skip forward in the agenda because people will be scheduling their time based on the agenda. Instead, the committee agreed to stay on schedule by taking a break or by accepting questions/issues on standards from the audience. However, the topics will be limited to those not addressed later in the NELAC Vi agenda. The committee had no other comments on the agenda for NELAC Vi.

Comments

The QS committee's approach to handling comments was addressed by the board. The amended letters (in response to comments) proposed by the board were acceptable to the committee.

Quantitation Limits

The chair requested that "quantitation limit" be struck out of section D1.4f. This section is the only use of "quantitation limit" in the version submitted for NELAC Vi.

Action Item from the Board

At the request of the board and the Membership and Outreach committee, the QS committee considered expanding the answer to Question 2. Currently, Question 2 and the answer are:

> "Do the QS standards require the use of any specific method? No."

The committee agreed not to include performance-based measurement systems (PBMS) in the response to Question 2, but to include a reference to Question 3 which does address PBMS. The response that the committee agreed to is as follows:

> "No, QS does not require the use of a specific method/s. Chapter 5 allows the user to select an appropriate method. However, regulatory agencies may mandate the use of a specific method (See also Question 3)."

Current Status of Chapter 5

The committee did not express any problems with the latest version of Chapter 5 which was submitted for NELAC Vi. However, the chair wants to be sure that Ms. Jane Jensen's comments regarding Mr. Porterfield's changes are addressed. Dr. George Kulasingam will bring her comments to NELAC Vi for discussion during the radiochemical testing session. Ms. Jensen was asked if she could provide alternative language as part of her comments. The chair expects that her comments will result in more discussion during the radiochemical testing session.

HOMEWORK

Topics discussed at this meeting involving comments received by the QS committee are detailed below:

Section 5.10.6 "Computers and Electronic Data Related Requirements"

The committee discussed possible revisions to Section 5.10.6 "Computers and Electronic Data Related Requirements." The committee agreed that the reference to "Good Automated Laboratory Practices" (1995) in 5.10.6a was redundant with the detail provided in parts 5.10.6 Section a through e and could therefore be deleted. In addition, the committee agreed that the GALP reference did not belong in 5.10.6a . The GALP reference was too limiting because it only addresses Laboratory Information Management Systems (LIMS). The committee discussed a number of options for revising this section and agreed to the revision below which Mr. Slayton will submit to Dr. Fred Siegelman for inclusion in the version of Chapter 5 available at NELAC Vi. The committee agreed that this change can be discussed at NELAC Vi.

5.10.6 Computers and Electronic Data Related Requirements

Where computers or automated equipment, microprocessors, as well as, laboratories employing Laboratory Information Management Systems are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:

a) all requirements of this Standard (i.e. Chapter Five) are met;

~~Sections 8.1 through 8.11 of the EPA Document "2185 - Good Automated Laboratory Practices" (1995), shall be adopted as the standard for all laboratories employing microprocessors, computers, as well as laboratories employing Laboratory Information Management Systems~~.

b) computer software is tested and documented ~~and~~ to be adequate for use;

The committee also discussed deleting the word "reporting" from the first paragraph of Section 5.10.6. The committee concluded that if "reporting" was deleted this year, it would need to be revisited next year as reporting becomes more prevalent. The consensus was to maintain the term "reporting."

ADDITIONAL COMMENTS

At the conclusion of the meeting, the committee briefly reviewed the status of several comments that are documented in the "Comments to the QS Committee Log & Status Table." The table will be updated to indicate that the following comments have been addressed: Comment 2 from Ms. Elsie Munsell (U.S. Navy), comment 6 from Mr. Steve Axelrod (Hillsborough Co. Water Dept.), and comment 7 from Ms. Jackie Sample (DOD).

In response to one comment from the Pennsylvania Department of Environmental Protection (PA DEP), the chair referenced Section D.3.8.c.2. This section will appear in the current version as follows:

> The sterilization temperature, cycle time, sterilization time, and pressure of each run of autoclaves must be documented by the use of appropriate chemical and or biological sterilization indicators. Autoclave tape may be used to indicate by color change that a load has been processed, but not to demonstrate completion of an acceptable sterilization cycle. Demonstration of sterilization shall be provided by a continuous temperature recording or with the use of spore strips at least once a month.

Comment #3 from Mr. George Avery refers to Section 5.9.42.2.e.ii, "Continuing Instrument Calibration Verification." The teleconference concluded on this topic, which the committee was asked to consider dropping entirely or dropping the word "maximum" for the next meeting.

QS TELECONFERENCE SCHEDULE

The following QS Committee teleconference is scheduled before NELAC V5i:

DATE(S)	TIME(S) EASTERN
Dec. 7	11 a.m.- 1 p.m.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
NOVEMBER 23, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Slayton will follow-up with Ms. Lisa Doucet and Mr. Porterfield regarding a conference line to allow Mr. Porterfield to participate in the Radiochemical Testing session at NELAC Vi.	December 3, 1999
2.	Dr. Siegelman will include the updates to Chapter 5 for NELAC Vi provided by Mr. Slayton.	December 3, 1999
3.	Mr. Slayton will update the comment "homework" table.	November 23, 1999

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE MEETING
NOVEMBER 23, 1999

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Attachment C

PARKING LOT ITEMS/ISSUES
QUALITY SYSTEMS COMMITTEE

Items/issues will remain in the Parking Lot until they are completed.

The following items were added to the parking lot following the November 24, 1999 meeting:

1. Review terms in Chapter 5 for terms needing clarification, e.g., “such as,” “independent standard,” “alternate source,” “second” or “alternate source.”

2. Combine “Analyst Training” and “Verification” into same section.

3. ~~Clarify “Custody” versus “Sample Tracking.”~~ Done

4. ~~Finalize Radiochemistry section~~. Done

5. ~~Come to closure on Air Testing issues.~~ Done

Attachment D

FREQUENTLY ASKED QUESTIONS
QUALITY SYSTEMS COMMITTEE
NOVEMBER 23, 1999

Some Frequently Asked Questions Concerning NELAC QS (Chapter 5):

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No, QS does not require the use of a specific method/s. Chapter 5 allows the user to select an appropriate method. However, regulatory agencies may mandate the use of a specific method (See also Question 3).

3. Question: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

6. Question: Why are we revisiting the calibration and detection parts of the standards?

Answer: At NELAC IV the Quality Systems Committee received numerous comments that the calibration and detection parts of the standards were too prescriptive and were not consistent with a PBMS environment. The Committee has attempted to propose changes to the calibration and detection parts of the standards that provide essential elements for those two quality system standards and that will support the anticipated needs of PBMS. The Committee believes the proposed language is less prescriptive (i.e., more flexibility), yet hopefully still ensures the quality of the analytical data.

In making these proposed changes the Committee has attempted to balance the need for more flexibility in the standards with the desire to not go to far and introduce excessive flexibility that could prove to be too vague or ill-advised. The Committee is currently discussing and considering its proposed language and public comments on the proposed language changes. The Committee is committed to assuring that the NELAC Quality Systems standards provide a foundation for PBMS implementation.

7. Question: Several States have indicated that it is very desirable that a laboratory already be actively analyzing samples for a particular program and by a method for which they want to be accredited. However, these same states have relayed that this ideal scenario is often not the case, as a laboratory may request accreditation in attempts to expand their scope of analytical services or in order to satisfy contractual requirements. These states ask: How will the QS standards help ensure that laboratories will have sufficient data for an onsite assessment especially given the proposed changes to the MDL section?

Answer: The MDL, section D.1.4, in the 1998 NELAC standards has a requirement that "MDLs" be determined initially (40 CFR Part 136, Appendix B) and be verified yearly by the analysis of at least one clean matrix sample spiked at the current reported MDL. Under the proposed revision to Section D.1.4, "Detection Limits" are to be determined initially and each time there is significant change in the test method or instrument type. The proposed standard still requires "MDL" if required in the mandated test method or applicable regulation. If the MDL is not required a "detection limit" must still be determined. Therefor the new section D.1.4 requirements should still help assure that performance data will be available for review by inspectors . In addition, laboratories are required to successfully complete two out of three PT samples yearly and this data would be available for review, as per section 5.5.4 and Chapter 2) . However, under the current PT requirements this may only include one method of multiple methods employed by a laboratory for a given parameter group, e.g., metals.

Laboratories also must perform an Initial Demonstration of Analytical Capability (5.10.2.1, D.1.3 Method Evaluation and Appendix C) . This data would be available for on-site review. Also note that the QS committee plans to expand Appendix C (IDC) procedures prior to NELAC V to make it applicable to methods for which spiking is difficult or impossible, e.g., Total Suspended Solids, which should further ensure that performance data is available for review.

In addition under Section 5.6.2.3.c. of QS, the Laboratory Management must ensure that the training of personnel is kept up-to-date, which includes a analyst certification to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year: I. acceptable performance of a blind sample (single blind to the analyst); ii. another initial demonstration of method capability; iii. successful analysis of a blind performance sample on a

similar test method using the same technology; iv. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; vi if I-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable. These requirements should further help assure performance data is available on-site for review.

Attachment D

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Attachment E

ACKNOWLEDGMENT LETTER, REVIEW GUIDELINES, AND COMMENTER TEMPLATE
QUALITY SYSTEMS COMMITTEE
NOVEMBER 23, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (topic listing) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,

Joseph Slayton, Chair
Quality Systems Committee

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following topic listing:

Comment ID #: Date:

Commenter's Name:
Affiliation:

Email Address:

Committee Lead on Response (Name):

Comment #1: Standard Rev. # , SECTION#

TO BE COMPLETED BY THE COMMENTER:

A: Current Standard Text

B: COMMENT with Rationale

C: Proposed Wording Change

TO BE COMPLETED BY THE COMMITTEE:

D: OUTCOME (Including any proposed change)

E: RATIONALE

Comment #2: Standard Rev. #, SECTION#

TO BE COMPLETED BY THE COMMENTER:

A: Current Standard Text

B: COMMENT with Rationale

C: Proposed Wording Change

TO BE COMPLETED BY THE COMMITTEE:

D: OUTCOME (Including any proposed change)

E: RATIONALE